K042405

OCT 14 2004

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stryker®
Instruments

510(k) Summary

Trade Names: Stryker PainPump1 and Stryker PainPump2

Common Name: Infusion Pump; Electromechanical Ambulatory Infusion Pump

Classification Name: Pump, Infusion, PCA

Equivalent to: K031249, Stryker PainPump1; K030661, PainPump2, K040337; I-Flow Elastomeric Pump w/ Bolus

Device Description:

PainPump1
PainPump1 is a disposable syringe infuser which uses sustained vacuum pressure to deliver a continuous infusion of medication to the patient for pain management an/or antibiotic delivery. Medication is delivered to the treatment site using an hourly flow rate. The routes of administration may be intramuscular or subcutaneous.

PainPump2
PainPump2 is an electromechanical pump designed to deliver controlled amounts of medication to the patient for pain management and/or antibiotic delivery. Medication is delivered to the treatment site using an hourly flow rate or combination of hourly flow rate and bolus PCA (Patient Controlled Analgesia) dosing option. The routes of administration may be intramuscular or subcutaneous.

Indications for Use:

PainPump1
The Stryker PainPump1 delivers controlled amounts of medication directly to the intraoperative site for pain management and/or antibiotic administration. The pump infuses the medication at an hourly flow rate. Medications are infused through intramuscular or subcutaneous routes.

The Stryker PainPump1 is also intended for controlled delivery of local anesthetics in close proximity to nerves for postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, or percutaneous.

The Stryker PainPump1 is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

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PainPump2

The Stryker PainPump2 delivers controlled amounts of medication directly to the intraoperative site for pain management and/or antibiotic administration. The pump infuses the medication at an hourly flow rate and provided the option for patient controlled bolus doses. Medications are infused through intramuscular, or subcutaneous routes.

The Stryker PainPump2 is intended for controlled delivery of local anesthetics in close proximity to nerves for postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, or percutaneous.

The Stryker PainPump2 is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Submitted by: Jennifer Mars
Regulatory Affairs Representative

Jennifer Mars
Signature

Date submitted: October 13, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 2004

Ms. Jennifer Mars
Regulatory Affairs Representative
Stryker Corporation
Instrument Division
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K042405
Trade/Device Name: PainPump1 and PainPump2
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: August 31, 2004
Received: September 7, 2004

Dear Ms. Mars:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042405

Indications for Use Statement

510(k) Number: K042405

Device Name: Stryker PainPump: PainPump1 and PainPump2

Indications for Use:

PainPump1 delivers controlled amounts of medication directly to the intraoperative site for pain management and/or antibiotic administration. The pump infuses the medication at an hourly flow rate. Medications are infused intraoperatively and postoperatively through intramuscular or subcutaneous routes.

PainPump1 is also intended for controlled delivery of local anesthetics in close proximity to nerves for postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, or percutaneous.

PainPump1 is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

PainPump2 delivers controlled amounts of medication directly to the intraoperative site for pain management and/or antibiotic administration. The pump infuses the medication at an hourly flow rate and provides the option for patient controlled bolus doses. Medications are infused intraoperatively and postoperatively through intramuscular or subcutaneous routes.

PainPump2 is also intended for controlled delivery of local anesthetics in close proximity to nerves for postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, or percutaneous.

PainPump2 is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) OR Over-The- Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042405